DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

October 1, 1996

RE: THE FDA EXPORT REFORM AND ENHANCEMENT ACT OF 1996

Dear Correspondent:

For several years, U.S. manufacturers of devices have voiced concern about the restrictions against exportation of unapproved products required by the Food Drug and Cosmetic (FD&C) Act. Manufacturers felt that they were being forced to move manufacturing of unapproved devices to foreign sites because FDA did not authorize exportation in a timely manner. The rising concern about potential job losses motivated the Congress to enact legislation, which was signed by President Clinton on April 26, 1996.

The new law (The FDA Export Reform & Enhancement Act of 1996) is designed to ease restrictions on exportation of unapproved devices. It also requires FDA to issue export certifications and authorizes the agency to charge firms for the certifications, provided that they are processed within 20 days. The funds collected for this service can now be used by FDA to offset some of the costs associated with certification.

EXPORT CERTIFICATION

Manufacturers exporting devices are often asked by foreign governments to provide a certificate that states the device is legally marketed in the United States. In the past, the certificate has been limited to an official attestation that the device and the system by which it is manufactured is in full compliance with the requirements of the FD&C Act.

Congress recognized that many importing countries rely heavily on certification as a means of assuring that imported devices are safe and effective. Congress also recognized the importance of facilitating trade by providing certification in a timely manner. In crafting the new export law, Congress provided authorization for FDA to issue export certificates not only for devices that are legally marketed but, also for devices that are not legally market in the United States but are acceptable to the importing country, as specified in Section 802 and 801(e)(1). The new export law now provides for three types of certificates. These are:

- **Certificates To Foreign Governments** were formerly issued under the title, Certificates For Products For Export. These certificates are issued for legally marketed devices that are in compliance with the requirements of the FD&C Act.

- o **Certificates Of Exportability (Section 802)** certify that unapproved devices are legally exported under the provisions of Section 802.

- o **Certificates Of Exportability [Section 801(e)(1)]** certify that devices that can not be legally marketed in the United States can be legally exported under the provisions of Section 801(e)(1).

Starting in FY 1994, the Center for Devices and Radiological Health (CDRH) initiated a new procedure for export certification. Manufacturers are required to self-certify that they are in compliance with all applicable requirements of the FD&C Act, not only at the time that they submit their request to CDRH but also at the time that they submit the certification to the foreign government. CDRH conducts a check on all information submitted by firms in support of their certificates. Any suspected case of fraud is referred to FDA's Office of Criminal Investigations for follow up.

The new export certification procedures have resulted in a dramatic reduction in the time required for processing requests for certification (from an average of 52 days in FY 1993 to 3.5 days in FY 1996), without diminishing the validity of the facts attested to by the certificates. Based on this success, CDRH will continue to rely on self-certification by manufacturers for all three types of certificates. As before, the information submitted by manufacturers in support of their requests will be independently verified.

The new export law authorizes FDA to charge $175.00 for each certificate. However, the streamlined self-certification procedures have reduced processing costs to the point where CDRH charges $100.00 for the first certificate and $10 for any subsequent certificates issued for the same product(s) in response to the same request. Requests submitted on or after October 1, 1996, will be charged retroactively. You should not send checks with your requests, as they will bill you each month for the total number of certifications issued to your firm during that period.

Detailed instructions for requesting each of the three types of certificates are attached. If you have any questions concerning the instructions please write or call 301-594-4520.

Sincerely yours,

Michele D. Hudson

Michele D. Hudson
Chief, Information Processing and
Office Automation Branch
Office of Compliance
Center for Devices and
Radiological Health

Effective 10/01/96
Interim procedures and instructions pending final agency approval.

INSTRUCTIONS FOR REQUESTS FOR CERTIFICATE TO FOREIGN GOVERNMENT

1. Complete the "Exporter's Certification Statement" and the "Supplementary Information Sheet". Please ensure that you sign the Exporter's Certification Statement.

2. Using the attached example (**Attachment A**), prepare on plain white 8 1/2" x 11" bond paper, the Certificate to Foreign Government (**print margin one inch, top margin two inches, 44 lines per page**). You may also submit this information on a standard IBM compatible 3 1/2" diskette using Word Perfect 5.1 software/Microsoft Word. Diskettes received will be scanned for viruses using an anti-virus scanning program. In addition, diskettes submitted will not be returned.

3. Provide typed lists of products (**please provide complete device description as it appears in the 510(k)**) on consecutively numbered 8 1/2" x 11" sheets of paper. Do not submit catalogs or catalog pages. Indicate under "PRODUCTS" heading on the certificate "See attached list (**number of pages**)."

4. Enclose a self-addressed stamped envelope or FEDEX envelope large enough to accommodate the requested Certificate(s).

5. Send the request and supporting documents to:

   Food and Drug Administration
   Center for Devices and Radiological Health
   Office of Compliance
   Attention: HFZ-307
   2094 Gaither Road
   Rockville, Maryland 20850

6. Clearly mark on the outside of the envelope containing the request as a "Request for Certificates." If you have any questions, please call 301-594-4520.

7. We do not certify Foreign Manufacturers; therefore, please provide the name and address of the U.S. Initial Distributor (**P.O. Box not acceptable**).

8. You may be required to submit proof that a device was offered for sale prior to May 28, 1976 showing preamendment status. Copies of catalog pages or other written proof may be sent with your Certificate request to speed processing.

9. As of October 1, 1996, CDRH has the authority to charge $100 for the first certificate and $10 for any subsequent certificates issued for the same product(s) in response to the same request. Requests submitted on or after October 1, 1996, will be charged retroactively. Please **do not** submit a check with your request, as FDA will bill you each month.

10. The Certificate to Foreign Government (**Attachment A**) may be copied and used for subsequent shipments, as long as an original Foreign Country Certification Statement (**Attachment B**) is attached to it.

EXPORTER'S CERTIFICATION STATEMENT

As a responsible individual authorized to represent and act on behalf of _____ (requesting company), I hereby certify to the Food and Drug Administration (FDA) that the company and the products identified on the attached application for a Certificate to Foreign Government, are to the best of my knowledge in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the Act), and all applicable or pertinent regulations enforced by the FDA as follows:

1. _____ (requesting company) is currently registered and has listed each of its medical devices identified for export as required by Section 510 of the Act and 21 CFR Part 807 (see attached Supplementary Information);

2. Each product identified for export is sold within the United States and is the subject of a 510(k) premarket notification or is a device that was in commercial distribution before May 28, 1976, or is the subject of a premarket approval application;

3. The products identified are not subject of an open recall or the subject of any current enforcement action initiated by FDA; and

4. _____ (requesting company) is currently operating in substantial compliance with the Good Manufacturing Practices Regulation (21 CFR Part 820) for the identified products.

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submission of false statements represent violations of United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to five years imprisonment.

_____
Typed Name and Signature

_____
Title

SUPPLEMENTARY INFORMATION

1. Registration number, firm name and location of manufacturing/distribution site in the U.S.

2. Marketing status of each product to be included in the Certificate.

Product	510(k) Number and Date of Substantial Equivalence Letter	PMA Number and Date of Approval Letter	Exempt/ Preamendment*

* Documentation may be required to prove preamendment status for a device that was offered for sale prior to May 28, 1976.

3. List country(ies) for which Certificates are requested.

4. Mail Certificate(s) to:

5. If different from Number 4 send Invoice to:

6. Firm Tax Identification Number.

EXAMPLE

ATTACHMENT A

Certificate No.

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

NAME OF PRODUCT(S) (GENERIC NAME IF APPLICABLE)	**NAME OF MANUFACTURER/DISTRIBUTOR, ADDRESS**

The product(s) described above (and the manufacturing site(s) which produces it) is subject to the jurisdiction of the FDA.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Michele D. Hudson, Chief
Information Processing and
Office Automation Branch
Office of Compliance
Center for Devices and
Radiological Health

This certificate expires 36 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this ____ day of _____month_____year.

_____

ATTACHMENT B

FOREIGN COUNTRY CERTIFICATION STATEMENT

As a responsible official of _____, I hereby certify that the company and products identified in the attached Certificate to Foreign Government continue to be, to the best of my knowledge, in compliance with the Federal Food, Drug, and Cosmetic Act and all applicable or pertinent regulations enforced by the U.S. Food and Drug Administration. A photocopy of the Certificate to Foreign Government may be used as long as this original statement is attached.

_____
Signature

_____
Typed Name and Title

Subscribed and sworn to before me this ___ day of _____month,_____year.

_____

INSTRUCTIONS FOR REQUESTS FOR CERTIFICATE OF EXPORTABILITY (SECTION 802)

1. Complete the "Exporter's Certification Statement" and the "Supplementary Information Sheet". Please ensure that you sign the Exporter's Certification Statement.

2. Using the attached example (**Attachment C**), prepare on plain white 8 1/2" x 11" bond paper, the Certificate of Exportability (Section 802) (**print margin one inch, top margin two inches, 44 lines per page**). You may also submit this information on a standard IBM compatible 3 1/2" diskette using Word Perfect 5.1 software/Microsoft Word. Diskettes received will be scanned for viruses using an anti-virus scanning program. In addition, diskettes submitted will not be returned.

3. Provide typed lists of products on consecutively numbered 8 1/2" x 11" sheets of paper. Do not submit catalogs or catalog pages. Indicate under "PRODUCTS" heading on the certificate "See attached list (**number of pages**)."

4. Enclose a self-addressed stamped envelope or FEDEX envelope large enough to accommodate the requested Certificate(s).

5. Send the request and supporting documents to:

   Food and Drug Administration
   Center for Devices and Radiological Health
   Office of Compliance
   Attention: HFZ-307
   2094 Gaither Road
   Rockville, Maryland 20850

6. Clearly mark the outside of the envelope containing the request as a "Request for Certificates." If you have any questions, please call 301-594-4520.

7. We do not certify Foreign Manufacturers; therefore, please provide the name and address of the U.S. Initial Distributor (**P.O. Box not acceptable**).

8. As of October 1, 1996, CDRH has the authority to charge $100 for the first certificate and $10 for any subsequent certificates issued for the same product(s) in response to the same request. Requests submitted on or after October 1, 1996, will be charged retroactively. Please **do not** submit a check with your request, as FDA will bill you each month.

9. The Certificate of Exportability (Section 802) (**Attachment C**) may be copied and used for subsequent shipments, as long as an original Foreign Country Certification Statement (**Attachment D**) is attached to it.

EXPORTER'S CERTIFICATION STATEMENT

As a responsible individual authorized to represent and act on behalf of _____ (requesting company), I hereby certify to the Food and Drug Administration (FDA) that the company and the products identified on the attached application for a Certificate of Exportability (Section 802), are to the best of my knowledge in compliance with the Federal Food, Drug, and Cosmetic Act (the Act), and all applicable or pertinent regulations enforced by the FDA as follows:

1. _____ (requesting company) is currently registered and has listed each of its medical devices identified for export as required by Section 510 of the Act and 21 CFR Part 807 (see attached Supplementary Information);

2. Each product(s) identified for export is manufactured substantially in accordance with good manufacturing practices or international quality systems standards recognized by the Secretary; 802(f)(1) (At this time, the Secretary has not recognized any international quality system standards.)

3. Each product(s) identified is not adulterated by containing any filthy, putrid or decomposed substance; 501(a)(i)

4. Each product(s) identified is not prepared, packed or held under insanitary conditions whereby it may be contaminated with filth or rendered injurious to health; 501(a)(2)(A)

5. Each product(s) container does not contain any poisonous or deleterious substance which may render the device injurious to health; 501(a)(3)

6. Each product(s) identified for export accords to the specification of the foreign purchaser; 801(e)(1)

7. Each product(s) identified is not in conflict with the laws of the country to which it is intended for export; 801(e)(1)

8. The shipping package for the product(s) is labeled on the outside that it is intended for export; 801(e)(1)

9. The product(s) is not sold or offered for sale in domestic commerce (the United States); and 801(e)(1)

10. The product(s) identified is not an imminent hazard to health; 802(f)(4)(B)

11. The product(s) identified are labeled in accordance with the requirements of the Tier 1 Country that granted marketing authorization, as well as the requirements of any other country to which the device would be exported (including language requirements and units of measure).

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submission of false statements represent violations of United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to five years imprisonment.

_____
Typed Name and Signature

_____
Title

SUPPLEMENTARY INFORMATION CERTIFICATE OF EXPORTABILITY (Section 802)

1. Registration number, firm name and location of manufacturing/distribution site in the U.S.

2. Mail Certificate(s) to:

3. If different from Number 2 send Invoice to:

4. Firm Tax Identification Number.

5. List country(ies) for which Certificates are requested.

Effective 10/01/96
Interim procedures and instructions pending final agency approval.

EXAMPLE

ATTACHMENT C

Certificate No.

CERTIFICATE OF EXPORTABILITY (SECTION 802)

The Food and Drug Administration certifies that the product(s) described below is subject to its jurisdiction under the Federal Food, Drug, and Cosmetic Act (the Act). Such product(s), which is not approved for marketing in the United States, may be legally exported provided it meets the requirements of Section 802 of the Act.

Under Section 802 of the Act, a drug or device not approved for marketing in the United States may be exported if it is manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed below. The company has certified to the Food and Drug Administration that:

* the product(s) accords to the specifications of the foreign purchaser;
* the product(s) is not in conflict with the laws of the country to which it is intended for export;
* the shipping package for the product(s) is labeled on the outside that it is intended for export; and
* the product(s) is not sold or offered for sale in the United States.

Based on the information above, the product(s) listed below may be exported pursuant to Section 802 of the Act.

NAME OF PRODUCT
[GENERIC NAME IF APPLICABLE]

NAME OF COMPANY, ADDRESS

Michele D. Hudson, Chief
Information Processing and
Office Automation Branch
Office of Compliance
Center for Devices and
Radiological Health

This certificate expires 36 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this ____ day of _____ month _____ year.

_____

ATTACHMENT D

FOREIGN COUNTRY CERTIFICATION STATEMENT

As a responsible official of _____, I hereby certify that the company and products identified in the attached Certificate of Exportability (Section 802) continue to be, to the best of my knowledge, in compliance with the Federal Food, Drug, and Cosmetic Act and all applicable or pertinent regulations enforced by the U.S. Food and Drug Administration. A photocopy of the Certificate of Exportability (Section 802) may be used as long as this original statement is attached.

_____
Signature

_____
Typed Name and Title

Subscribed and sworn to before me this ___ day of _____ month _____ year.

_____

Effective 10/01/96
Interim procedures and instructions pending final agency approval.

INSTRUCTIONS FOR REQUESTS FOR CERTIFICATE OF EXPORTABILITY (SECTION 801(e)1)

1. Complete the "Exporter's Certification Statement" and the "Supplementary Information Sheet". Please ensure that you sign the Exporter's Certification Statement.

2. Using the attached example (**Attachment E**), prepare on plain white 8 1/2" x 11" bond paper, the Certificate of Exportability (Section 801(e)1) (**print margin one inch, top margin two inches, 44 lines per page**). You may also submit this information on a standard IBM compatible 3 1/2" diskette using Word Perfect 5.1 software/Microsoft Word. Diskettes received will be scanned for viruses using an anti-virus scanning program. In addition, diskettes submitted will not be returned.

3. Provide typed lists of products on consecutively numbered 8 1/2" x 11" sheets of paper. Do not submit catalogs or catalog pages. Indicate under "PRODUCTS" heading on the certificate "See attached list (**number of pages**)."

4. Enclose a self-addressed stamped envelope or FEDEX envelope large enough to accommodate the requested Certificate(s).

5. Send the request and supporting documents to:

   Food and Drug Administration
   Center for Devices and Radiological Health
   Office of Compliance
   Attention: HFZ-307
   2094 Gaither Road
   Rockville, Maryland 20850

6. Clearly mark the outside of the envelope containing the request as a "Request for Certificates." If you have any questions, please call 301-594-4520.

7. We do not certify Foreign Manufacturers; therefore, please provide the name and address of the U.S. Initial Distributor (**P.O. Box not acceptable**).

8. As of October 1, 1996, CDRH has the authority to charge $100 for the first certificate and $10 for any subsequent certificates issued for the same product(s) in response to the same request. Requests submitted on or after October 1, 1996, will be charged retroactively. Please **do not** submit a check with your request, as FDA will bill you at the end of each month.

9. The Certificate of Exportability (Section 801(e)1) (**Attachment E**) may be copied and used for subsequent shipments, as long as an original Foreign Country Certification Statement (**Attachment F**) is attached to it.

Effective 10/01/96
Interim procedures and instructions pending final agency approval.

EXPORTER'S CERTIFICATION STATEMENT

As a responsible individual authorized to represent and act on behalf of _____ (requesting company), I hereby certify to the Food and Drug Administration (FDA) that the company and the products identified on the attached application for a Certificate of Exportability (Section 801(e)1), are to the best of my knowledge in compliance with the Federal Food, Drug, and Cosmetic Act (the Act), and all applicable or pertinent regulations enforced by the FDA as follows:

1. Each product(s) identified for export accord to the specification of the foreign purchaser; 801(e)(1)

2. Each product(s) identified are not in conflict with the laws of the country to which it is intended for export; 801(e)(1)

3. The product(s) shipping package for the product(s) is labeled on the outside that it is intended for export; 801(e)(1) and

4. The product(s) is not sold or offered for sale in domestic commerce (the United States); and 801(e)(1)

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submission of false statements represent violations of United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to five years imprisonment.

_____
Typed Name and Signature

_____
Title

SUPPLEMENTARY INFORMATION
CERTIFICATE OF EXPORTABILITY (Section 801(e)1)

1. Registration number, firm name and location of manufacturing/distribution site in the U.S.

2. Mail Certificate(s) to:

3. If different from Number 2 send Invoice to:

4. Firm Tax Identification Number.

5. List country(ies) for which Certificates are requested.

EXAMPLE

ATTACHMENT E

Certificate No.

CERTIFICATE OF EXPORTABILITY (SECTION 801(e)1)

The Food and Drug Administration certifies that the product(s) described below is subject to its jurisdiction under the Federal Food, Drug, and Cosmetic Act (the Act). The products described below may not be sold or offered for sale in the United States. The company has certified to the Food and Drug Administration that:

* the product(s) accords to the specifications of the foreign purchaser;

* the product(s) is not in conflict with the laws of the country to which it is intended for export;

* the shipping package for the product(s) is labeled on the outside that it is intended for export;and

* the product(s) is not sold or offered for sale in the United States.

Based on the information above, the product(s) listed below may be exported pursuant to Section 801(e)1 of the Act.

NAME OF PRODUCT
[GENERIC NAME IF APPLICABLE]

NAME OF COMPANY, ADDRESS

Michele D. Hudson, Chief
Information Processing and
Office Automation Branch
Office of Compliance
Center for Devices and
Radiological Health

This certificate expires 36 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this ____ day of _____ month _____ year.

_____

_____

Effective 10/01/96
Interim procedures and instructions pending final agency approval.

ATTACHMENT F

FOREIGN COUNTRY CERTIFICATION STATEMENT

As a responsible official of _____, I hereby certify that the company and products identified in the attached Certificate of Exportability (Section 801(e)1) continue to be, to the best of my knowledge, in compliance with the Federal Food, Drug, and Cosmetic Act and all applicable or pertinent regulations enforced by the U.S. Food and Drug Administration. A photocopy of the Certificate of Exportability (Section 801(e)1) may be used as long as this original statement is attached.

_____
Signature

_____
Typed Name and Title

Subscribed and sworn to before me this ___ day of _____ month _____ year.

_____

_____
Effective 10/01/96
Interim procedures and instructions pending final agency approval.